

Consumers and the Dietary Supplement Marketplace

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Overview

- **Dietary Supplement Health and Education Act (DSHEA) of 1994**
- **Excluded “supplements” from regulation as drugs or drug products**
- **FDA must prove product is unsafe before product removed**

Dietary Supplements

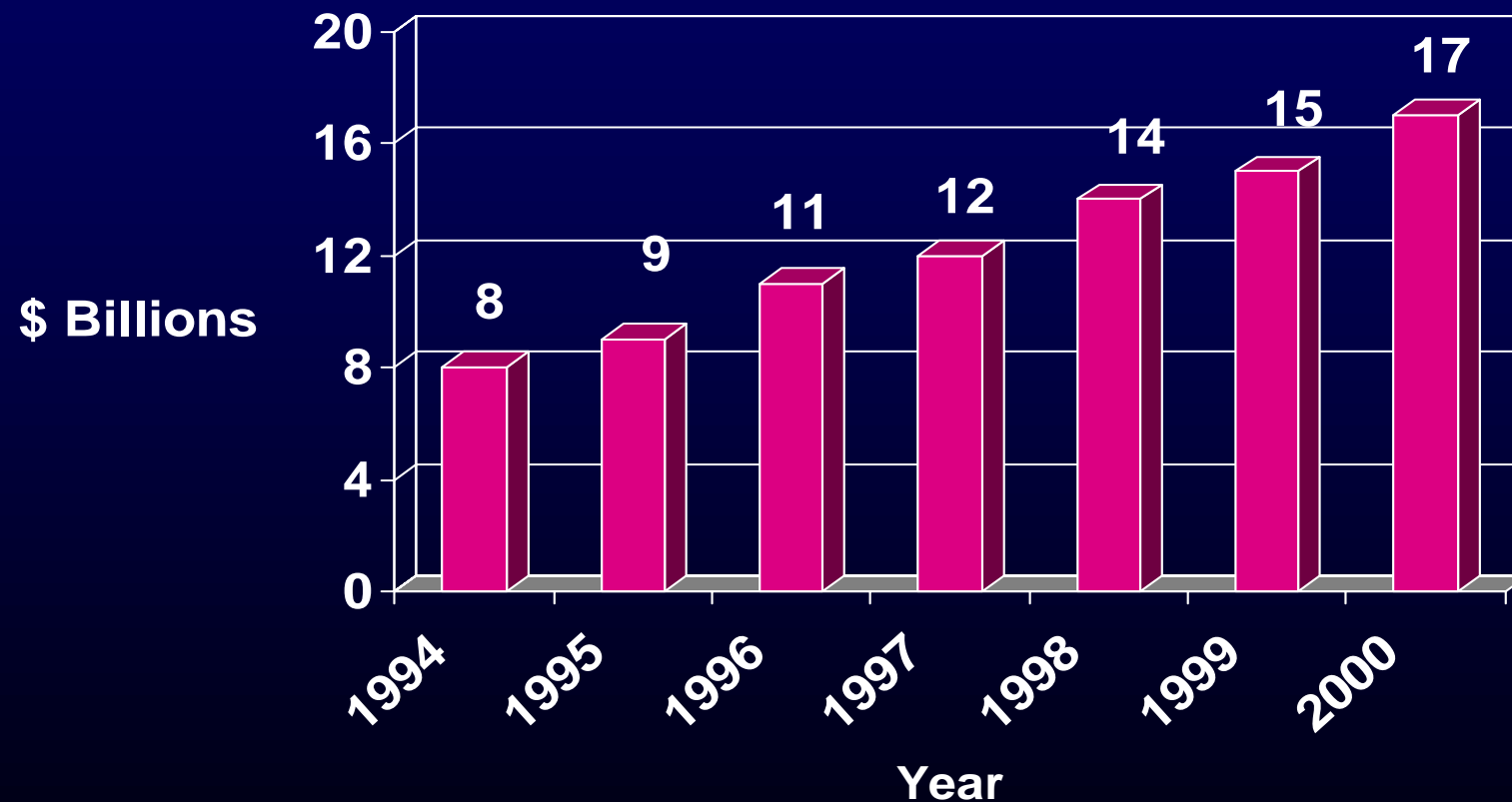
- **FDA definition**

Vitamins, minerals, herbs, amino acids and any other dietary supplements

- **Other definitions**

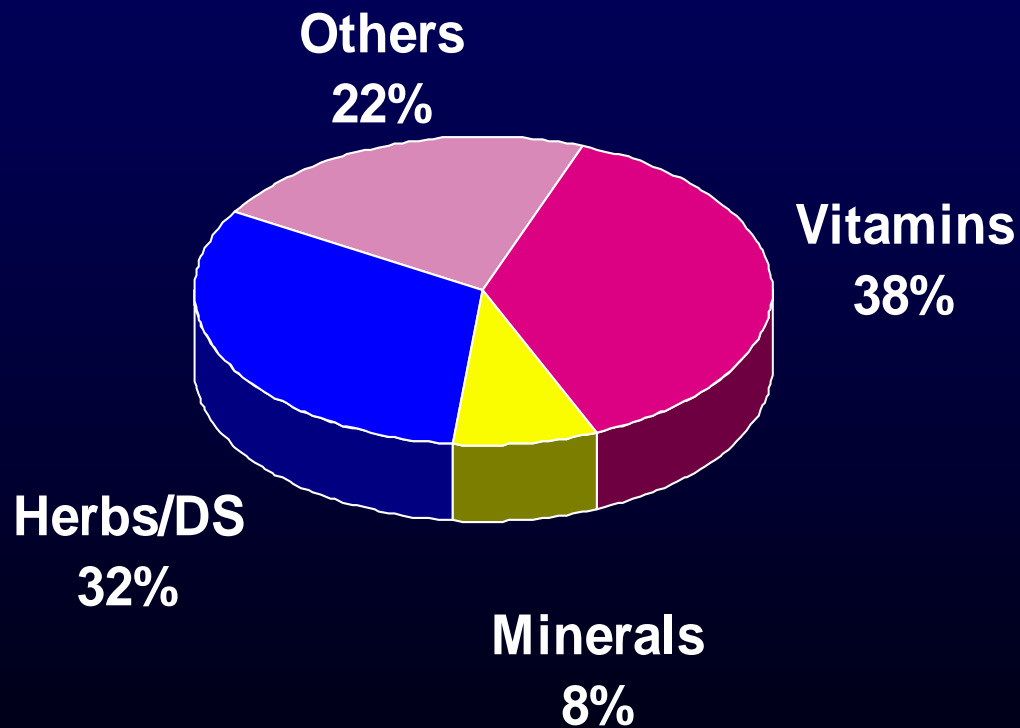
- » Herbs are plant derived (botanicals)
- » Dietary supplements (nutritional supplements) include all others
 - Cofactors
 - Vitamins
 - Hormones
 - Enzymes
 - Amino acids

Dietary Supplement Sales



Dietary Supplement Market

Year 2000 Dietary Supplement Sales



Good Manufacturing Practice

- **Products regulated under “Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food”**
- **Maintenance of buildings and facilities, food handler requirements and safety standards**
 - » **Building Maintenance**
 - » **Product Handler Requirements**

Labeling Requirements

- Statement of identity (e.g., "ginseng")
- Net quantity of contents (e.g., "60 capsules")
- Structure-function claim and the statement:
"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Labeling Requirements

- **Directions for use**
- **Supplement Facts panel**
 - » **lists serving size, amount, and active ingredient**
- **Other ingredients**
 - » **In descending order of predominance and by common name or proprietary blend**
- **Name and address of manufacturer, packer or distributor**

Supplement Facts Panel

GNC CALCIUM COMPLETE

Serving Size Three Tablets	
Servings Per Container 30	
Amount Per Serving	% Daily Value
Vitamin C (as Ascorbic Acid)	300 mg 500%
Calcium (as Calcium Carbonate)	1200 mg 120%
Magnesium (as Magnesium Oxide)	600 mg 150%
Betaine Hydrochloride	50 mg *
* Daily Value not established.	
Other Ingredients: Cellulose, Soy Fiber, Titanium Dioxide	
(Natural Mineral)	

POSSIBLE DV CONFUSION
120% of Daily Value for calcium sounds good—but some post-menopausal women will need to take 300 mg more to meet NIH recommendations.

UPPER DOSAGE LIMITS EXCEEDED

This supplement exceeds the 350 mg daily tolerable upper intake levels for Magnesium set by the National Academy of Sciences. High doses may cause diarrhea.

Identifying Fraudulent Claims

- Any product that carries the following wording:
 - » Breakthrough
 - » Magical
 - » Miracle Cure
 - » New Discovery
- Pseudo-medical jargon
 - » Purify
 - » Detoxify
 - » Energize

Identifying Fraudulent Claims

- Any product that claims it can cure a wide range of unrelated medical conditions
- Claims that the product has only benefits and no side effects
- Lack of scientific references or ones that are out of date
- Any product that claims it has been hidden from the public by government, the medical profession or other organizations

Advertising Claims



Health Care Implications

- **Products are considered by some as mainstream**
- **Many misconceptions**
- **Consumers may or may not be dissatisfied with their health care**
- **These products are more consistent with their life-style**

The Issues

- Increased use has led to increased emphasis on interactions
- Surgical patients frequently use herbal products and rarely disclose their use
- Various surveys estimate:
 - » 22% presurgical patients routinely use herbs
 - » 51% presurgical patients routinely use vitamins
 - » 8% report taking multiple herbs
 - » 27% of patients use herbs that can interfere with blood clotting

Predictors for Use

- Survey of presurgical patients in five California hospitals
- Average age between 35-49
- Females > Males
- Level of education: completed professional school, college educated
- Predominantly Caucasian, Asian and Hispanic
- Average yearly household income >\$60,000

Predictors for Use

- More likely to use if patients also had:
 - » sleep disturbance
 - » joint or back problems
 - » allergies
 - » drug dependence
 - » history of general surgical procedures

Non-Disclosure of Use

- In 1993 nondisclosure estimated at 70%
- In 1998 nondisclosure estimated at 40%
- People are more likely to disclose use if seeking care for different problem
- Periodic health review
 - » 30% disclosed use on a form
 - » 61% disclosed use in direct interview (only if asked)
- Multiple reasons for non-disclosure

Reasons for Non-Disclosure

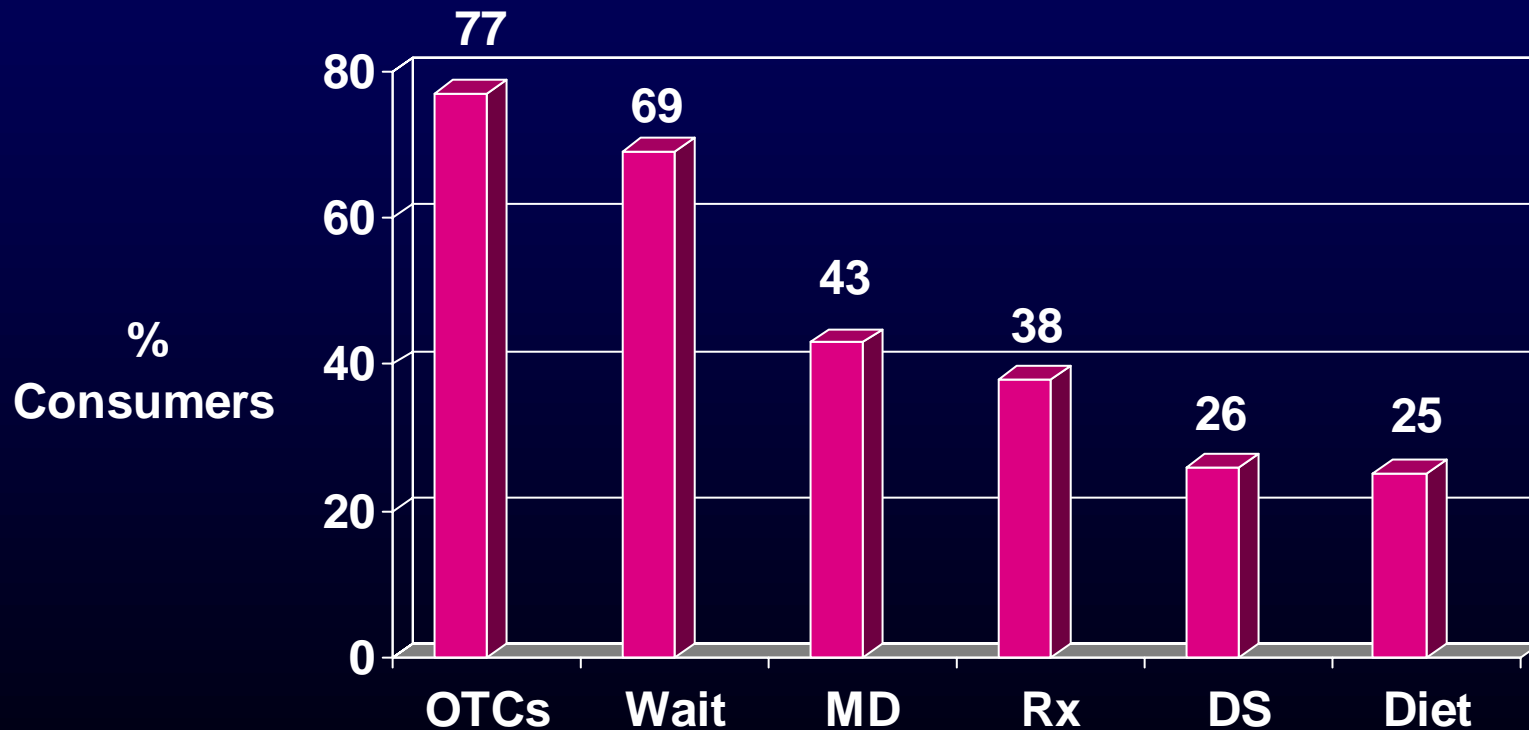
- Impression of disinterest
- Anticipation of a negative response
- Perception that physician is unable or unwilling to contribute helpful information
- CAM therapies irrelevant to medical care
- Coordination of care is personal choice

Side Effect Reporting

- Frequency of reporting is low (4.3%)
- Most will stop taking the herb; others will seek medical attention; of these only a few are reported
- Users are less likely to attribute adverse event to herb (26%) than to a drug (30%)
- Users from health food store less likely to report adverse event at all

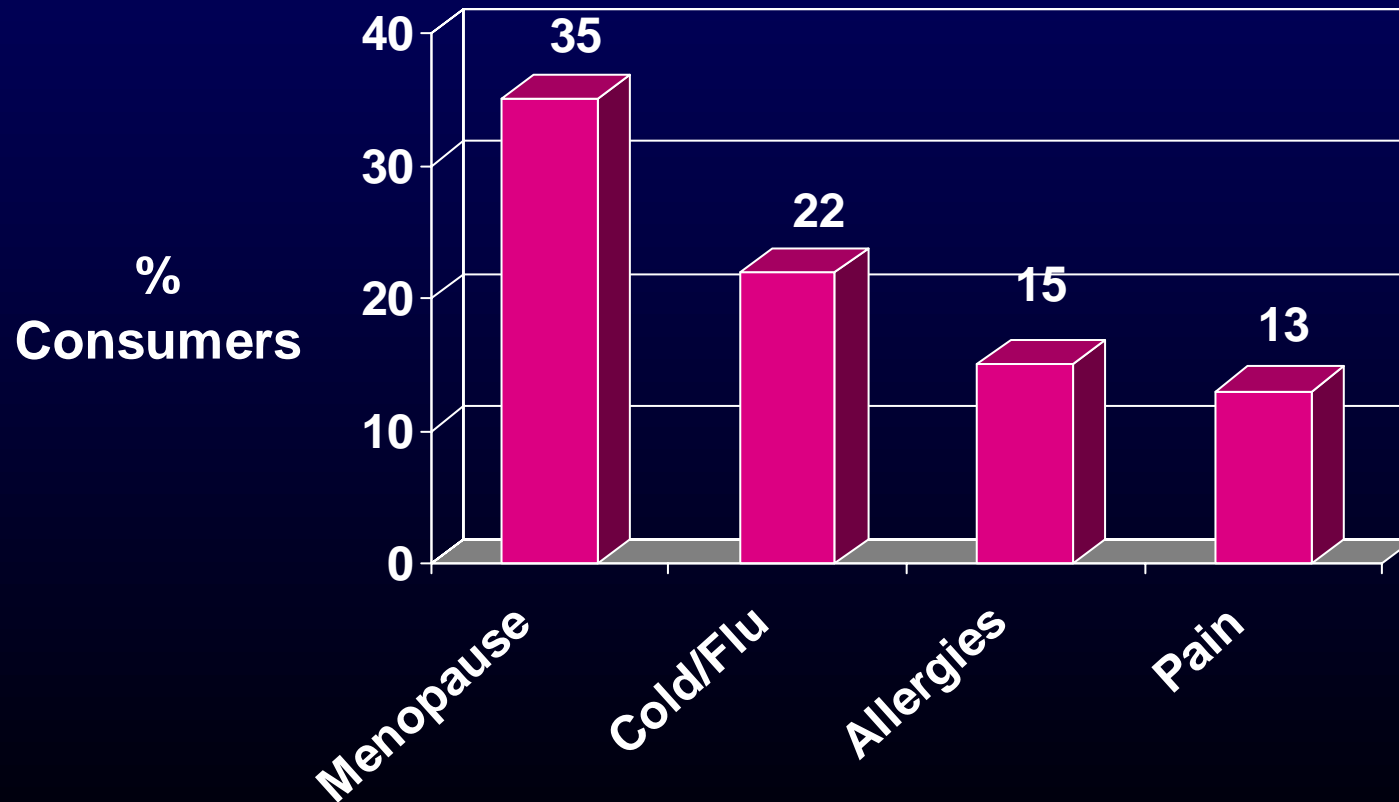
Consumer Behavior

What do consumers do when they get sick?

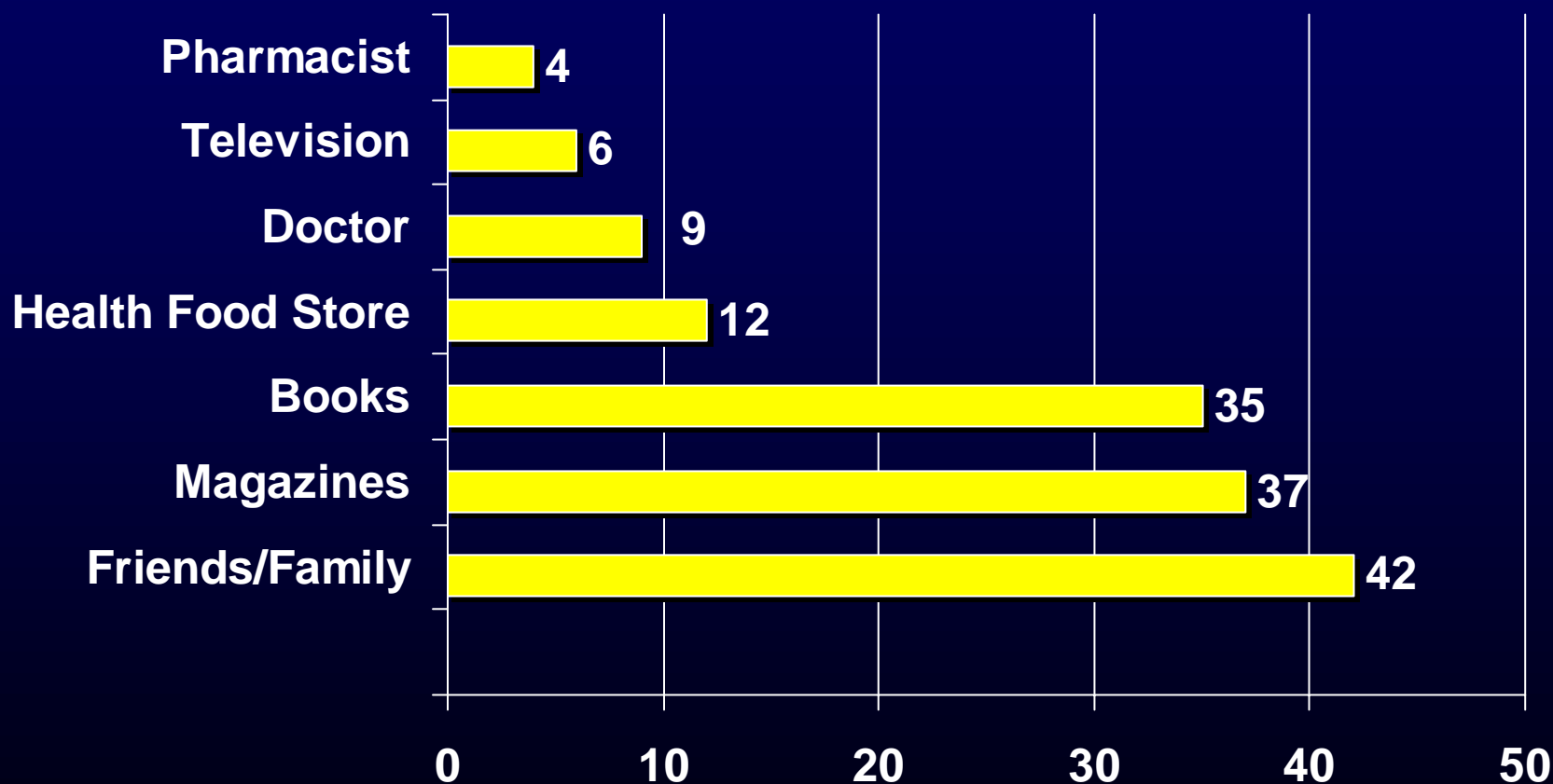


Consumer Behavior

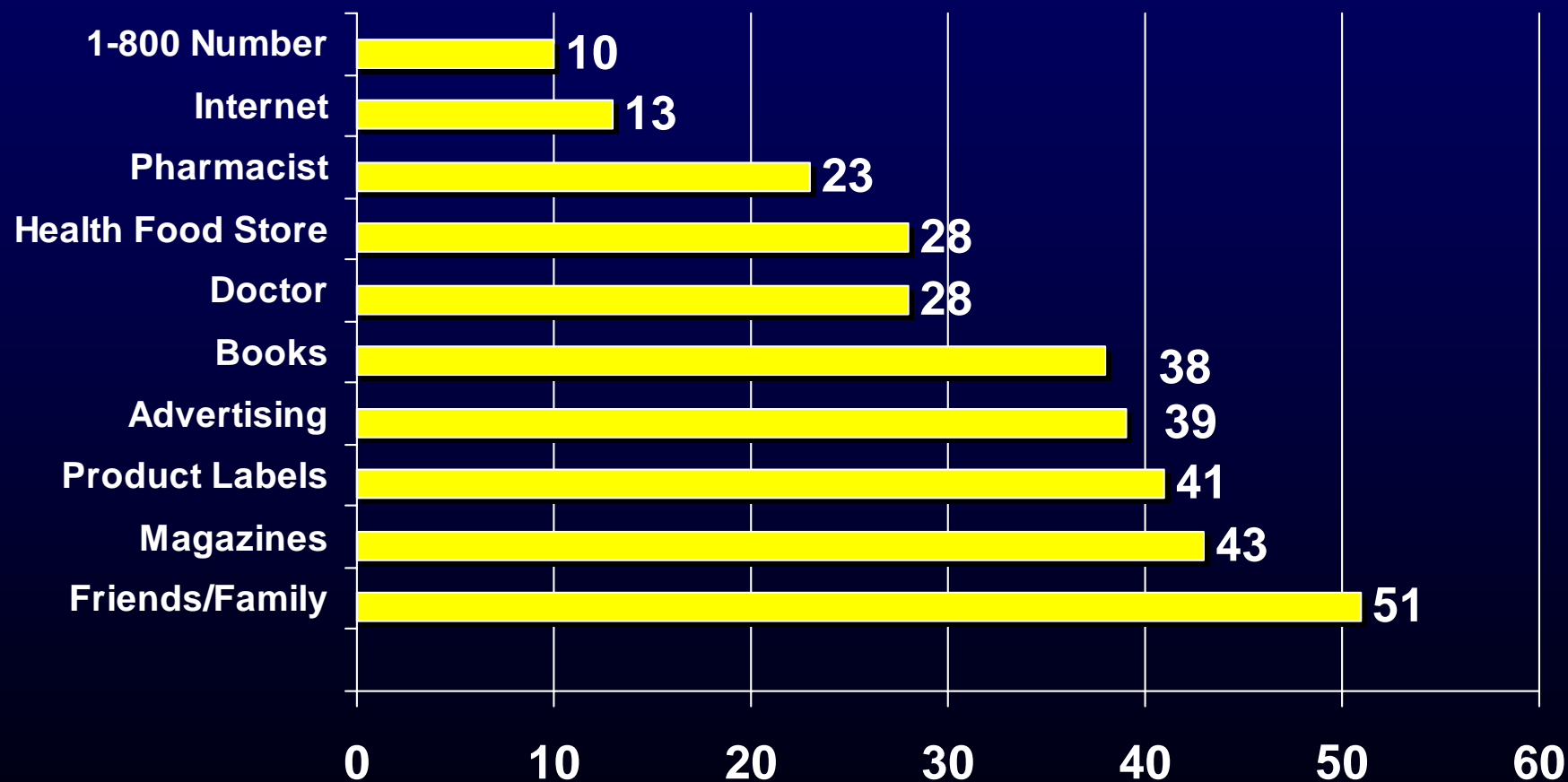
What are the most popular reasons for using DS?



Where Consumers Get Information



Where Consumers Get Information



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Prevention, 1999

Your Health Care Provider's Role

- They should ask and document it in your medical record
- Consumers are quite savvy: they should not dismiss the issue
- Three-tiered model for use or RTA approach
 - » Recommend
 - » Tolerate
 - » Avoid
- Provide monitoring guidelines
- Help patients set realistic goals

FDA Warnings

- The FDA posting warnings of contaminated or harmful supplements
- Tiratricol or TRIAC (triiodothyroacetic acid)
- Aristolochic acid
- FDA advisory to remove comfrey products from the market
- FTC announcements to take action against any marketing related to comfrey including that on the Internet
- Ephedra alkaloids

Ephedra

- Ephedra is an herb derived from the shrub *Ephedra sinica*
- Contains many active components; one of which is ephedrine
- Ephedrine has a variety of actions on the body
- Used for weight loss to decrease appetite and increase metabolism
- Hundreds of serious effects and at least 80 deaths

Ephedra

- Series of articles reviewing the ephedra cases
- Lots of publicity in the press
- Various states have set labeling/sales regulations
- Many law suits brought against some of the top manufacturers
- Liability insurance premiums have increased
- Bush Administration ordered an independent review of ephedra expected in March 2003
- Now ephedra-free products being sold

Adverse Reaction Reporting

- The Office of Inspector General prepared a report on the status of dietary supplements adverse effects through the MedWatch program
- Found limited:
 - medical information
 - product information
 - manufacturer information
 - consumer information
 - ability to analyze trends

Adverse Reaction Reporting

- **Facilitate greater detection of adverse events**
 - » **Mandatory manufacturer reporting**
 - » **Include Poison Center reports**
 - » **Notify consumers/remind professionals to report**
- **Obtain more information on each report**
 - » **Detailed medical information**
 - » **Manufacturer registration with FDA**
 - » **Product registration with FDA**
 - » **Notify manufacturers of serious FDA reports**
 - » **New database for tracking**

Institute of Medicine Report

- FDA attempting to set up a regulatory system; asked IOM for a review of the dietary supplement industry
- IOM created and recommended guiding principles in establishing a framework for FDA review of potentially unsafe products
- First priority supplements for evaluation:
 - » Chaparral
 - » Chromium picolinate
 - » Glucosamine
 - » Melatonin
 - » Saw palmetto
 - » Shark cartilage

USP NF

- **United States Pharmacopoeia/National Formulary**
- **Non-profit corporation that sets standards for drugs and biologics**
- **Creating standards for botanicals and other dietary supplements**
 - » **Heavy metal content (e.g. Lead content in ppm)**
 - » **Bacteria (*Staph/E. coli*)**
 - » **Pesticide residues**
 - » **Contaminants**
 - » **Product conformity testing**

Consumer Perceptions

- Q: If a government agency said that a particular supplement was ineffective, what would you do?
 - » A. Stop using the supplement 25%
 - » B. Keep using the supplement 72%
 - » C. Do not know 3%

Consumer Perceptions

- Q: Should dietary supplements be removed from the market if the FDA shows they are unsafe?

»A. Yes	79%
»B. No	19%
»C. Do not know	1%

Consumer Perceptions

- **Q: Should NEW dietary supplements be sold only after they have been tested by the FDA ?**

»A. Yes	80%
»B. No	17%
»C. Do not know	3%

Consumer Perceptions

- Increased federal regulation to ensure safety
- Increased FDA authority to remove unsafe products from the market
- Increased authority for FTC and FDA to intervene on false or misleading advertising claims

The Need for Evidence

- **National Institutes of Health (NIH) funded 12 National Complimentary and Alternative Medicine (NCCAM) specialty centers**
- **Each coordinating research in the area of specific CAM modalities**
- **Various systematic reviews and meta-analyses conducted to assess existing studies**
- **Prospective RCT studies are underway for glucosamine, kava and various others**

Resources

- **Tips For the Savvy Supplement User: Making Informed Decisions and Evaluating Information**

<http://www.cfsan.fda.gov/~dms/supplmnt.html>

- **United States Pharmacopoeia (USP) created the Dietary Supplement Verification Program**

<http://www.usp-dsvp.org>

- **Consumer Lab**

www.consumerlab.com

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
Dietary Supplements
January 2000

Tips For The Savvy Supplement User: **Making Informed Decisions And Evaluating Information**

FDA, as well as health professionals and their organizations, receive many inquiries each year from consumers seeking health-related information, especially about dietary supplements. Clearly, people choosing to supplement their diets with herbs, vitamins, minerals, or other substances want to know more about the products they choose so that they can make informed decisions about them. The choice to use a dietary supplement can be a wise decision that provides health benefits. However, under certain circumstances, these products may be unnecessary for good health or they may even create unexpected risks.

Given the abundance and conflicting nature of information now available about dietary supplements, you may need help to sort the reliable information from the questionable. Below are tips and resources that we hope will help you be a savvy dietary supplement user. The principles underlying these tips are similar to those principles a savvy consumer would use for any product.

- [Basic Points to Consider](#)
- [Tips on Searching the Web for Information on Dietary Supplements](#)
- [More Tips and To-Do's](#)

Note: Links to non-Federal government organizations found on this site are provided solely as a service to consumers and do not represent an FDA endorsement of these organizations or their products. (For resources see [Selected References](#).)

Basic Points to Consider

• Do I need to think about my total diet?

Yes. Dietary supplements are intended to supplement the diets of some people, but not to replace the balance of the variety of foods important to a healthy diet. While you need enough nutrients, too much of some nutrients can cause problems. You can find information on the functions and potential benefits of vitamins and minerals, as well as upper safe limits for nutrients at the National Academy of Sciences Web site at: <http://www.nas.edu/jom/jomhome.nsf/Pages/FNB+Reports>

• Should I check with my doctor or healthcare provider before using a supplement?

This is a good idea, especially for certain population groups. Dietary supplements may not be risk-free under certain circumstances. If you are pregnant, nursing a baby, or have a chronic medical condition, such as, diabetes, hypertension or heart disease, be sure to consult your doctor or pharmacist before purchasing or taking any supplement. While vitamin and mineral supplements are widely used and generally considered safe for children, you may wish to check with your doctor or pharmacist before giving these or any other dietary supplements to your child. If you plan to use a dietary supplement in place of drugs or in combination with any drug, tell your health care provider first. Many supplements contain active ingredients that have strong biological effects and their safety is not always assured in all users. If you have certain health conditions and take these products, you may be placing yourself at risk.

- **Some supplements may interact with prescription and over-the-counter medicines.**

Taking a combination of supplements or using these products together with medications (whether prescription or OTC drugs) could under certain circumstances produce adverse effects, some of which could be life-threatening. Be alert to advisories about these products, whether taken alone or in combination. For example, Coumadin (a prescription medicine), ginkgo biloba (an herbal supplement), aspirin (an OTC drug) and vitamin E (a vitamin supplement) can each thin the blood, and taking any of these products together can increase the potential for internal bleeding. Combining St. John's Wort with certain HIV drugs significantly reduces their effectiveness. St. John's Wort may also reduce the effectiveness of prescription drugs for heart disease, depression, seizures, certain cancers or oral contraceptives.